

Ethics and Childhood Vaccination Policy in the United States

Childhood immunization involves a balance between parents' autonomy in deciding whether to immunize their children and the benefits to public health from mandating vaccines. Ethical concerns about pediatric vaccination span several public health domains, including those of policymakers, clinicians, and other professionals.

In light of ongoing developments and debates, we discuss several key ethical issues concerning childhood immunization in the United States and describe how they affect policy development and clinical practice. We focus on ethical considerations pertaining to herd immunity as a community good, vaccine communication, dismissal of vaccine-refusing families from practice, and vaccine mandates.

Clinicians and policymakers need to consider the nature and timing of vaccine-related discussions and invoke deliberative approaches to policymaking. (*Am J Public Health*. 2016;106:273–278. doi:10.2105/AJPH.2015.302952)

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Following the December 2014 measles outbreak at a popular amusement park in California,^{1,2} which spread to other states, Canada, and Mexico, there has been increased attention to US childhood immunization practices. A recent study attributed the outbreak to underimmunization,³ and several policymakers have called for an end to religious and philosophical (i.e., personal-belief) exemptions altogether, with the state of California passing legislation removing the option of personal-belief exemptions.^{4,5} Political candidates have expressed various viewpoints on vaccination.⁶ In light of these developments, we discuss several key ethical issues concerning childhood immunization in the United States and describe how they affect policy development and clinical practice. There are a myriad of ethical issues regarding such topics as vaccination development, administration, communication, and safety monitoring. We focus on a few key ethical issues concerning childhood immunization in the United States—what we refer to as a “vaccine ethics” approach—and describe how such an approach affects policy development and clinical immunization practice.

VACCINE ATTITUDES AND BEHAVIORS

In a time of growing hesitation, uncertainty, and opposition concerning childhood vaccines,

the developed world is witnessing a resurgence of vaccine-preventable illnesses.^{7–9} Although the spread of antivaccine and vaccine-fear sentiments has become common through social networks, both online and in person,^{10,11} a growing body of research argues that such sentiments are multidimensional and nuanced.^{12,13}

Although sensible public policy is often consistent with public sentiment, there are instances in which empirical data can give conflicting input about the ethical acceptability of policy. In vaccine policy, this is especially true when one distinguishes behaviors from attitudes. Although related to one another, attitudes about vaccination may differ from actual behaviors; indeed, they can at times be orthogonal constructs that interact uniquely depending on individual and contextual factors. For example, a mother who seeks vaccination for herself and her children is exhibiting provaccine behavior, but may nonetheless feel hesitant or uncertain about vaccines. In this case, her behavior may be a response to school-entry requirements and employer policies. In contrast to her provaccine behavior, however, her

underlying vaccine-hesitant attitudes about vaccination may be driven by religious reasons, skepticism about science, or the influence of personalities she trusts on other matters.

A different mother may hold provaccination attitudes, but may not vaccinate herself or her children because of access barriers such as difficulties securing transportation to a health care provider or inability to pay for vaccination. Moreover, some parents may resist particular vaccines rather than all vaccines.¹⁴ They may mistakenly believe that vaccination is appropriate for others but not for their children or family, perhaps believing that they are invulnerable to an illness.^{15,16} Thus, studies that capture either attitudes or behaviors, but not both, provide an incomplete portrait of the larger vaccination landscape. It is the group of parents who both hold vaccine-opposing (or vaccine-hesitant) attitudes and exhibit nonvaccinating behavior that are the primary focus of this essay. This is the group that is at the center of the “public health vs personal choice” debate.

Some may believe that a few nonvaccinating parents will have

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no appreciable impact on outbreak likelihood or management. Although this belief might seem at least somewhat justified for some diseases that may be eliminated or nearly eradicated (such as polio) or that have relatively low levels of transmissibility, it is not justifiable for highly infectious diseases like measles. It does not take many unvaccinated individuals to approach the tipping point at which vaccine coverage levels are too low and are thus ineffective in preventing disease spread. This tipping point is called “herd immunity” or “community immunity.”^{17,18} For measles, the herd immunity threshold is somewhat fragile in that it requires a large proportion (96%–99%) of a given population to be vaccinated to confer maximal protection.^{19,20} Importantly, when that critical threshold of immunity is achieved, the benefits of preventing the spread of an infectious illness also extend to those who cannot themselves be vaccinated (e.g., young infants), the immunocompromised (e.g., those undergoing chemotherapy), those for whom immunity may have gradually worn off over time, or those who have incomplete vaccination status. Illustrating this concept, news headlines have recently featured stories of individuals who are immunocompromised and whose avoidance of vaccine-preventable illnesses lies in herd immunity—that is, in the hands of others who chose to vaccinate (or not).²¹

THE TRAGEDY OF THE (HERD IMMUNITY) COMMONS

Some scholars liken the anti-vaccine movement to a type of “free-rider” problem²²

reminiscent of Hardin’s iconic 1968 “Tragedy of the Commons.”^{23,24} The analogy would work as follows: a population that is appropriately vaccinated against highly infectious diseases is a common good to the very society of which its members are a part. Like Hardin’s fields that must be maintained and replenished over time, the failure of which depletes the community resources, so too must a community maintain its immunity to ensure its health and wellness. Maintaining this common good requires that all vaccine-eligible individuals be vaccinated. However, some individuals refuse to vaccinate themselves and their children for nonmedical reasons. Ultimately, as with Hardin’s Tragedy of the Commons, as more individuals behave in a manner that fails to consider the common good, there is a detrimental effect on the overall well-being of the group and, therefore, on the well-being of each individual, including those individuals who chose to forgo vaccination. More specifically, in the case of childhood immunizations, the individual interest at stake is the parents’ right to refuse immunization for their children, with the refusal often-times based on inaccurate information or lack of understanding of the safety and efficacy of vaccines. One may question whether deference to individual parental decisions extends to situations in which the parents’ decision is (1) factually baseless and (2) potentially detrimental to the health of both the children and the community.

There is evidence that forgoing vaccination for oneself because others are vaccinated (free-riding) is evident in some adults’ vaccine decisions for themselves.^{22,25–27} However, published data are mixed or

unclear regarding both the effectiveness of communicating to the public the societal benefits of immunization and the prevalence of free-riding among parents deciding about vaccination for their children.^{28–31} Some parents do invoke the herd immunity argument as a reason not to vaccinate, suggesting that it is unnecessary that they expose their child to the risk of side-effects from vaccination if everyone else is vaccinated to a level that prevents the spread of illnesses.³² Parental decision-making about vaccination lends itself to analysis using game theory,³³ which we will not pursue here, except to support the notion suggested by Shim et al. that vaccination decisions are not simply selfish or selfless but may involve complex relationships between these motivations.³⁴

This degradation of the community resource of herd immunity is portrayed in stark reality in the recent California measles outbreak. Furthermore, when we consider data documenting geographic clusters of underimmunization around the United States,³⁵ it becomes clear that some locations have not attained thresholds necessary to stop vaccine-preventable illness outbreaks, putting people—especially unvaccinated young children, the immunocompromised, and the elderly—at increased risk for contracting an illness.

VACCINE ETHICS, THE PUBLIC’S HEALTH, AND PERSONAL CHOICE

Vaccine ethics can be conceptualized as a set of issues at the intersection of public health policy, clinical ethics, and professional ethics. The ethical

implications concerning vaccine-related public health policy are numerous and at the forefront of much recent discussion—for example, mandating vaccines for school entry and excluding unvaccinated children from schools in the case of outbreaks. Worth noting is that US vaccine policy decisions can have ethical implications for other countries. For example, when the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices withdrew recommendations to give the rotavirus vaccine to 2-, 4-, and 6-month-old children in 1999 in response to rare intussusception cases,³⁶ it became difficult to distribute the vaccine in developing countries where rotavirus had much higher morbidity and mortality rates.^{37,38}

The ethics of public health policy surrounding childhood immunization extend to issues beyond individuals’ vaccination decisions; they also include issues such as vaccine mandates and how easily and by what process exemptions may be obtained. In an article published in March 2015, Gostin argues that vaccine mandates are a medium through which the social contract of public health is upheld.²⁴ He further contends that states offer exemptions for religious and philosophical reasons not out of legal concerns but out of politically motivated concerns.

Clinical and professional ethics emerge when deciding about how best to assess one’s ongoing responsibility to vaccine-refusing families in one’s primary care practice.^{39,40}

However, professional ethics also involve the judgment of non-clinicians, such as policymakers, public health personnel, and researchers; for example, in

determining how best to communicate with vaccine-hesitant families via public health messaging and how a researcher might communicate with vaccine-hesitant or vaccine-opposing study participants. Ethical questions in this vein include whether it is acceptable to leverage knowledge of human psychology to capitalize on phenomena like “anticipatory regret” to persuade or nudge individuals to engage in healthy behaviors such as vaccine uptake.

How can a vaccine ethics approach inform the debate about herd immunity? At its core, vaccination is an action that implicates several fundamental ethical principles. It invokes distributive justice insofar as benefits and burdens are allocated to those who vaccinate and those who do not. It requires society to resolve issues such as the following: Who bears the burden of vaccination and who benefits from herd immunity? Should individuals be allowed to benefit when others assume some level of risk (e.g., from vaccination) and they do not? It invokes beneficence and nonmaleficence precisely because the benefits and harms to individuals and communities are seen to be in dispute, and it speaks to the foundational importance of respect for personal autonomy insofar as individual choice (and, where children are involved, surrogate decision-making) is a hallmark of informed consent. In some ways, the herd immunity debate is about finding ways to honor the informed decisions that individuals wish to make while protecting those who are not capable of being vaccinated themselves.

Others have made similar observations. Relying on ethical principles outlined by Beauchamp and Childress⁴¹ and focusing on

human papilloma virus vaccination, Field and Caplan⁴² propose an ethical framework, characterizing vaccine mandates as a debate involving competing ethical values—specifically, the values of individual autonomy and the principles of beneficence, nonmaleficence, justice, and utilitarianism. Therefore, in a very real sense vaccination debates are similar to other types of decisions that constitute the unspoken social contract—membership in a community often places citizens in the position of supporting actions or policies judged to be for the overall benefit of society but that might contradict individual beliefs about what is in the best interests of a particular person.⁴²

Although we have focused on health care providers, public health personnel, and policymakers, we recognize that there are many other actors contributing to considerations surrounding vaccine ethics. For example, there is the consideration that regulatory bodies within a government have ethical responsibilities to monitor vaccines for safety after they are licensed,⁴³ which is an important means of fostering public trust.⁴⁴ However, the CDC’s funding for such monitoring has been historically limited compared with funding for purchasing and promoting immunizations.⁴⁴ The budget requested for the CDC’s Immunization Program, which includes safety monitoring, decreased by \$51.5 million from 2014 to 2015⁴⁵ and by \$50.3 million from 2015 to 2016.⁴⁶

Importantly, the perspective of patients and patients’ parents as immunization decision-makers is also critical. These individuals may or may not take into consideration social responsibility and how their choices affect the health of others. Ethical considerations include whether patients (or their parents) bear

a responsibility to consider that their immunization decisions can affect others. Is there a line to be drawn between respecting vaccine refusers’ choices and maximizing the greater good through herd immunity? Is there a responsibility on behalf of practitioners, policymakers, and researchers to be empathetic to the rationale underlying vaccine refusers’ decisions?

We have focused on the perspectives of policymakers and clinicians in a developed setting in which there is infrastructure to offer childhood immunizations, track administration, and enforce policies. In resource-limited settings, however, such infrastructure may not exist or individuals may not have opportunities to receive vaccines. To address this critical need and ethical obligation, there have been multiple calls for governments of developed and resource-limited countries to work together to improve childhood immunization coverage around the world.^{47,48}

Developing sound and informed policy, clinical practice, and ongoing research efforts will require incorporating the perspectives of all stakeholders in this milieu of vaccine considerations. Deliberative processes⁴⁹ may be an approach to incorporate the perspectives of various stakeholders, although reconciling diverse attitudes and recommendations is challenging.⁵⁰ One example of a deliberative approach focusing on public input is citizens’ juries,⁵¹ in which the public’s attitudes, beliefs, and recommendations are incorporated into policy decisions.

As with many public health problems, however, it is often difficult to satisfy all principles and professional obligations simultaneously. We consider this

problem in light of the current debate about family refusal of the measles vaccine.

PARENTS WHO REFUSE VACCINES

Families who refuse or resist vaccination for their children often defend their position on the basis that what they believe is in the best interests of their children.⁵² Their reasons vary, however, with some believing that vaccines will harm and not help or that vaccination is “unnatural” and “natural” immunity is preferable.⁵³ Others believe that they will enjoy herd immunity without subjecting their child to the risk of vaccinating (free-riding).²⁸ Still others may cite various nonmedical objections, ranging from the seemingly justifiable (e.g., that there is no need to vaccinate one’s children for eliminated illnesses) to conspiracy theories (e.g., that a government entity could be conducting intelligence-gathering operations under the auspices of a vaccination program).^{54,55} To some observers, these reasons are not equally defensible—it is one thing to reject vaccines because families believe it is inconsistent with their sincerely held religious beliefs (more defensible), but it is another to reject vaccines because of a belief in a government conspiracy (less defensible).

Similarly, there is a range of views regarding the appropriate response toward parents who take these positions. Some prominent bioethicists argue that nonvaccinators should be held accountable⁵⁶—legally liable^{57,58} and perhaps even financially responsible⁵⁹—for their decisions. There is a comparable argument that holds that parents should be held accountable for acting (or failing to—for example, when

a parent objects to a blood transfusion on religious grounds) in a manner that exposes their children to the risk of harm.⁶⁰

These arguments invoke many of the principles discussed in this essay. This is a distributive justice issue: everyone who is able should bear the burden of vaccination to receive the benefit of being protected from the spread of vaccine-preventable illnesses through herd immunity. It is also a matter of beneficence in that we should vaccinate to help protect those who cannot be vaccinated.^{42,57,59,61} Some legal scholars argue that, under tort remedy, as long as causality can be demonstrated (an admittedly difficult undertaking), there is a potential for recourse to hold nonvaccinators responsible should their failure to vaccinate lead to infecting others.⁵⁸ Arguments like these also invoke the concept of retributive justice—how to punish those who commit actions that may harm others.⁶² This line of thinking would consider such issues as the following: Should unvaccinated children be subject to distancing or exclusion policies, such as being prevented from going to school, participating in after-school sports, or holding jobs? Should parents who opt to forego vaccinations for their child have tax benefits withheld or reduced? There are corollary examples of adults who refuse to vaccinate themselves. In some instances, there are punitive measures for failure to vaccinate oneself—for example, health care workers facing employment termination for refusing influenza vaccination.⁶³

Related to the issue of whether to hold parents responsible for refusing vaccination, health care providers are debating the ethics of refusing to treat or dismissing from one's

practice families who refuse vaccines for nonmedical reasons. Encountering families who oppose some or all vaccines is common among physicians. In one survey, 54% of pediatrician respondents indicated they had encountered one or more families who opposed all vaccines.⁶⁴ Moreover, in this same survey, 39% of pediatricians said they would dismiss families who refused all vaccines, with 28% reporting they would dismiss families who refused some vaccines. More recent research has indicated that 25% of surveyed pediatricians say they would always, often, or sometimes dismiss families from their practice for refusing any vaccines in the primary childhood immunization series.⁶⁵ It has been long known and recently reiterated that nonvaccinating patients pose a risk to others in the waiting room, especially infants who are not yet old enough to be vaccinated or individuals whose immune systems are compromised.^{66,67}

Physicians' dismissal of vaccine-refusing families runs counter to recommendations from the American Academy of Pediatrics (AAP) Committee on Bioethics.^{68,69} The AAP stresses that health care providers should address vaccine refusal through hearing the family's concerns and discussing the risks that accompany not vaccinating one's child. They argue that each encounter with a vaccine-refusing family is an opportunity to describe the importance of vaccination—an opportunity lost if the family sought care elsewhere. The AAP position tries to craft a middle ground, acknowledging the positions held by parents and believing that ongoing engagement is better than disrupting or altogether severing the therapeutic relationship through dismissal.

RESOLUTION THROUGH BETTER COMMUNICATION

Ethical issues also underlie the emerging body of research on how best to communicate with vaccine-hesitant and vaccine-opposing families. Some argue that taking a "presumptive" approach during clinical encounters—in which the physician assumes the family will agree to recommended vaccinations—results in higher rates of vaccination uptake than with a "participatory" approach—in which the physician makes no such assumption and solicits the family's input on whether to vaccinate.^{70,71} Others have argued for a non-adversarial,⁷² "guiding" approach¹² in which the health care provider addresses the family's specific concerns to ultimately help them decide to vaccinate.

All 3 of these communication approaches have strengths and potential drawbacks. The presumptive approach is thought to result in less vaccine resistance among parents; however, some are concerned that, with the reduction or absence of shared decision-making, such approaches may make families feel that the provider does not care about their perspective or that their autonomy is being encroached on.^{12,73} Alternately, with the participatory and guiding approaches, patients could leave the provider's office unvaccinated for a period of time, perhaps putting children at risk for exposure to illness; however, health care providers and researchers argue that approaches like these are likelier to foster the therapeutic relationship between patients and their providers.¹² Moreover, related to the challenges and emotionally charged

nature of vaccine discussions, health care providers may feel moral distress⁷⁴ in determining the degree to which they should nudge vaccine-hesitant or opposing families to immunize their children. This moral distress would likely result from an ethical conflict between doing what the provider sees as best for the child and for society (i.e., vaccinating) and what is best for fostering the therapeutic relationship with that patient and the patient's family (i.e., respecting the family's wishes and not pushing the family too hard). Such distress is likely to be compounded by discomfort caused by counseling on an emotionally charged issue such as vaccination.

WHERE TO GO FROM HERE

Given the documented difficulty of communicating with vaccine-hesitant and vaccine-opposing families in a way that addresses their concerns and respects their autonomy, coupled with challenges in communicating the greater good of vaccinations in typical face-to-face clinical encounters, it is time to rethink how health care practitioners, policymakers, and communicators approach vaccine education and communication. From a policy and clinical ethics perspective, this might mean making the informed-consent process more educationally intensive and applicable not only to parents choosing to immunize their children but also, and especially, to those refusing or declining immunizations or requesting a modified schedule. Although findings regarding the impact of educational and messaging efforts on vaccine attitudes and intentions are mixed, one approach worth investigating

might be an informed opt-out process in which parents are presented with information regarding what it is like to see one's child suffer from a vaccine-preventable illness such as measles.⁷⁵

From a policy perspective, it may mean reevaluating the ease with which nonmedical exemptions are handled, with increased attention toward ensuring that parents are making informed decisions, especially when they opt out of vaccination. The state of California recently passed legislation that removes the option of personal belief exemptions.⁵ This has led to much public deliberation as to whether the state has overstepped its authority by encroaching on individual parental rights in the name of promoting public health, with some arguing that mandatory vaccinations also violate the Nuremberg Code.⁷⁶ We disagree with both of these claims. Regarding the former, it is precisely the business of state actors to make these decisions, and the acceptability of such decisions will be adjudicated at the ballot box. Regarding the latter, we fail to see how a 6-decade-old statement crafted after a military tribunal for unethical human experiments applies to the present case.

Given the reality of limited clinical encounter time and the challenges of tailoring large-scale public health media campaigns, it might make sense to illustrate concepts through other means of information transmission. For example, parents of pediatric patients could be directed to online video narratives of individuals describing their experiences with vaccine-preventable illnesses, or to decision-support instruments and educational Web sites that can present information that is targeted or,

ideally, tailored to parents' specific concerns. Researchers are developing and refining such tools.^{77,78} The timing of information provision could also be fine-tuned, adding prenatal visits as an opportunity for families and providers to discuss childhood immunizations as well as to identify opportunities and resources for vaccine education well before an infant's first vaccines.

Striking a balance between respecting parental rights and autonomy and maximizing the greater good of herd immunity may seem an intractable problem, especially in the current climate of heated vaccine debates. It undoubtedly calls for a multifaceted set of interventions; however, deliberate efforts must be made now. The alternative—permitting opinions and attitudes alone (which may be based on erroneous information or misperceptions) to support behavior—is as great a threat to public health as the unvaccinated population itself. Although this most recent measles outbreak has largely subsided, it is likely that another, potentially worse outbreak will occur. Developing sound policy now will help to reduce the severity of or altogether stop future outbreaks. Thus, as media attention to this subject waxes and wanes, we implore readers to keep the topic of vaccine policy and ethics at the forefront. **AJPH**

CONTRIBUTORS

K. S. Hendrix contributed to the essay's ideas and drafted, made revisions to, and submitted the manuscript. L. A. Sturm, G. D. Zimet, and E. M. Meslin contributed to the essay's ideas and made revisions to the article.

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